

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of the effect of ondansetron and dexamethason on QT interval prolongation in pediatrics undergoing cochlear implantation

Protocol summary

Summary

Purpose: Pediatrics candidate for cochlear implantation often need surgery at an early age. Administration of antiemetic drugs cause complications such as QT prolongation. Therefore we designed this study to evaluate the effect of drugs applied on QT prolongation. Methods: In this randomized controlled clinical trial 60 patients aged 6 months to 18 years, candidate for cochlear implantation were enrolled. Known cases of jervell lange nielson syndrome and patients with cardiac complications, ECG and electrolytes abnormalities, those who used drugs which caused QT prolongation and with family history of QT prolongation, were excluded from the study. 1 hour before the entrance of the patients to the operating room midazolam was administered 0.5-0.75 mg/kg orally and 0.05-0.1 mg/kg intravenously. 12 leads ECG was applied and baseline strips were taken for all participant. Fentanyl 2 ug/kg was administered as premedication. Sevoflurane 8% and atracorium (0.5mg/kg) was used for induction. Isoflurane 1.2% was applied as maintenance. Using the random number table patients were divided to 2 groups; group A who received dexamethasone (0.1mg/kg) and group B who received ondansetron (0.2 mg/kg). 5 and 15 minutes after drug administration ECG was performed and evaluated for QT prolongation and other abnormalities between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122031487N1**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

مهرداد Mesbah kiaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 346 5866

Email address

dr.mmesbah@gmail.com

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of ondansetron and dexamethason on QT interval prolongation in pediatrics undergoing cochlear implantation

Public title

The comparison of ECG changes of ondansetron and dexamethasone in cochlear implantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 6 months to 18 years

candidate for cochlear implantation. Exclusion criteria: Known case of jervell lange nielson syndrome; patients with any cardiac disease; ECG abnormalities; electrolyte abnormalities; usage of drugs which prolong the QT interval and family history of QT prolongation.

Age

From **6 months** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran university of medical sciences

Street address

school of Medicine, Iran university of medical sciences, Hemmat Highway

City

Tehran

Postal code**Approval date**

2017-03-01, 1395/12/11

Ethics committee reference number

IR.IUMS.REC 1395.9311174024

Health conditions studied**1****Description of health condition studied**

long QT syndrom

ICD-10 code

I45.8

ICD-10 code description

Other specified conduction disorders

Primary outcomes**1****Description**

Prolonged QT interval

Timepoint

5 and 15 minutes after drug administration

Method of measurement

ECG monitoring and calculated by the cardiologist

Secondary outcomes**1****Description**

Vomit

Timepoint

After the surgery

Method of measurement

inspection

2**Description**

Nausea

Timepoint

After the surgery

Method of measurement

inspection

3**Description**

Prolonged Tp-e interval

Timepoint

5 and 15 minutes after drug administration

Method of measurement

ECG monitoring and calculated by the cardiologist

Intervention groups**1****Description**

Intervention Group 1: Ondansetron(0.2 milligram per kilogram)

Category

Treatment - Drugs

2**Description**

Intervention Group2: Dexamethason (0.1 milligram per kilogram)

Category

Treatment - Drugs

3**Description**

Control Group: Patient's baseline ECG before

administration of drugs
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram hospital, Satarkhan street, Tehran
Full name of responsible person
Dr Reza Safaeian
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Reza Safaeian
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School of Medicine, Iran university of medical sciences, Hemmat Highway
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty